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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,557	05/02/2002	Audrey Goddard	GNE.3230R1C39	9770

20995 7590 01/08/2008

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EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	**PAPER NUMBER**
1643	

NOTIFICATION DATE	DELIVERY MODE
01/08/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/063,557	GODDARD ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 Septrember 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/7/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07 September 2007 has been entered.

2. Claim 6 is cancelled.

3. Claims 1-5 are pending and under consideration.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 07 September 2007 has been fully considered by the examiner. A signed and initialed copy of the IDS is included with the instant Office Action.

Rejections Maintained

6. The rejection of claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al (U.S. Patent 6,277,574 B1, 4/9/1999) is maintained.

The response filed 9/7/2007 again states that US Provisional Application Serial No. 60/088,740 filed June 10, 1998 discloses that SEQ ID NO:50 has homology to channel inhibitory factor and MAT-8, each of which is involved in ion conductance and applicant submits that the PTO has issued many patents based on homology of the claimed polypeptide to biologically relevant polypeptides, citing three issued U.S. Patents (Exhibits A-C) for support. Applicant concludes that the filing of US Provisional Application Serial No. 60/088,740 on June 10, 1998 is sufficient to demonstrate Applicants' conception and demonstration of utility prior to the April 9, 1999 effective date of the Walker reference. Applicants' arguments have been fully considered but are

not found persuasive. Again, the current record of the instant application establishes that the utility of the presently claimed polypeptide of SEQ ID NO:50 (PRO1069) is based on Example 18 at pg. 140 of the instant specification which shows that the PRO1069 cDNA (DNA59211) is more highly expressed in normal kidney compared to kidney tumor and applicants' submission of more than 140 references where expression levels of mRNA were found to have a good correlation to the expressed protein levels. Thus, Applicant is not relying upon homology to channel inhibitory factor and MAT-8 for utility and such has not been considered on the current record. Further, the timeliness of applicants' query with respect to homology is curious in view of the current record and the extensive arguments and resources previously exhausted in establishing utility of the presently claimed polypeptide based on Example 18 of the instant specification.

Applicant maintains that the previously submitted Declaration under 37 CFR 1.131 by Goddard et al filed 10/14/2005, which according to applicant is sufficient to establish conception of the claimed invention prior to June 10, 1998 coupled with diligent reduction to practice. Applicant argues that 37 CFR 1.131 does not require applicants to demonstrate utility of the claimed invention prior to the effective date of the Walker reference because the demonstration of utility is part of reduction to practice, not conception. Applicant refers to MPEP 715.07, which states "The affidavit or declaration must state FACTS and produce such documentary evidence and exhibits in support thereof as are available to show conception and completion of the invention in this country...**at least conception being at a date prior to the effective date of the reference**." MPEP 715.07 also states that the showing of facts must be sufficient to show "**conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice**." Applicant concludes that 37 CFR 1.131 only requires Applicants' to demonstrate conception prior to the effective date of the Walker reference. Applicant maintains that the filing of US Provisional Application Serial No. 60/088,740 on June 10, 1998 and the statements in the Declaration under 37 CFR 1.131 by Goddard et al filed 10/14/2005 establish that applicants' conceived of the sequence of the polypeptide of SEQ ID NO:50 prior to the effective date of the Walker

reference. Applicant refers to their previous response and the discussion of the Federal Circuit's decisions in *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 32 USPQ2d 1915 (Fed. Cir. 1994) and *Oka v. Youssefyeh*, 7 USPQ2d 1171 (Fed. Cir. 1998) which found that determination of utility is part of reduction to practice rather than conception. Applicants' arguments have been fully considered but are not found persuasive. Again, the issue in the present application is not whether utility is part of reduction to practice rather than conception, the issue is whether proof of utility must be shown if the reference discloses a utility and whether applicant has shown a utility prior to the effective date of the Walker reference. The cited case law of *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 32 USPQ2d 1915 (Fed. Cir. 1994) and *Oka v. Youssefyeh* are limited to determining whether utility is part of reduction to practice rather than conception. The examiner does not find the cited case law instructive to the facts in the present case, in which applicant is attempting to antedate a prior art reference based on conception where the prior art reference teaches the claimed compound and its utility. The examiner agrees that MPEP 715.07 states "The affidavit or declaration must state FACTS and produce such documentary evidence and exhibits in support thereof as are available to show conception and completion of the invention in this country...**at least conception being at a date prior to the effective date of the reference**." MPEP 715.07 also states that the showing of facts must be sufficient to show "**conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice**.", however, the examiner does not agree that 37 CFR 1.131 only requires Applicants' to demonstrate conception prior to the effective date of the prior art where the prior art also discloses a utility for the claimed compound. Again, the more relevant section of MPEP 715.07 is section III, which states that "One difference is that in interference practice a reduction to practice requires a proof that a utility was known, whereas under 37 CFR 1.131 practice, proof of a utility must be shown only if the reference discloses a utility. *In re Wilkinson*, 304 F.2d 673, 134 USPQ 171 (CCPA 1962); *In re Moore*, 444 F.2d 572, 170 USPQ 260 (CCPA 1971)." Thus, the MPEP in its own words, not the examiners (emphasis added), clearly instructs that "under 37 CFR

1.131 practice, proof of a utility must be shown only if the reference discloses a utility" (emphasis added). For convenience, it is reiterated that Walker et al teach a polypeptide sequence (SEQ ID NO:11; encoded by SEQ ID NO:5) that is identical to the claimed polypeptide sequence of SEQ ID NO:50 and antibodies thereto and the sequence of Walker is associated with kidney disease and is useful in the diagnosis; treatment and prognosis of diseases of the kidney (see entire document, particularly col. 11-14, 19, 22). Walker et al also claim the polynucleotide (i.e., SEQ ID NO:5), which encodes the polypeptide of SEQ ID NO:11, identical to the polypeptide claimed in the instant application. Thus, Walker et al disclosed the utility possessed by the polypeptide, which is more than what applicant has shown in US Provisional Application Serial No. 60/088,740, which is limited to the disclosure of the sequence of PRO1069. Applicant is reminded that under 37 CFR 1.131 practice, as stated in the MPEP "One difference is that in interference practice a reduction to practice requires a proof that a utility was known, whereas under 37 CFR 1.131 practice, proof of a utility must be shown only if the reference discloses a utility. *In re Wilkinson*, 304 F.2d 673, 134 USPQ 171 (CCPA 1962); *In re Moore*, 444 F.2d 572, 170 USPQ 260 (CCPA 1971)." See MPEP 715.07, section III. The Declaration under 37 CFR 1.131 by Goddard et al filed 10/14/2005 provides evidence that the utility upon which applicant relies for patentability, i.e., DNA59211 is more highly expressed normal kidney tissue than in kidney tumor, was not established until the experimental work of June 13, 2000, which is after the effective date of the Walker reference.

Applicants' arguments questioning the relevance of the cited case law of *In re Wilkinson*, 304 F.2d 673, 134 USPQ 171 (CCPA 1962) and *In re Moore*, 444 F.2d 572, 170 USPQ 260 (CCPA 1971) is curious given that the cited case law was copied directly out of MPEP 715.07, section III which states: "One difference is that in interference practice a reduction to practice requires a proof that a utility was known, whereas under 37 CFR 1.131 practice, proof of a utility must be shown only if the reference discloses a utility.".

For these reasons and those already of record, the rejection of claims 1-2 and 4-5 under 35 U.S.C. 102(e) as being anticipated by Walker et al is maintained.

7. The rejection of claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al (U.S. Patent 6,277,574 B1, 4/9/1999) in view of Queen et al (U.S. Patent 5,530,101, issued 6/96, cited previously on PTO-892 mailed 4/15/2004) is maintained.

The response filed 9/7/07 does not address the instant rejection and the rejections is maintained for reasons already of record and those reiterated above pertaining to the Walker et al reference.

8. No claim is allowed.

9. This is a continuation of applicant's earlier Application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643